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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,221	12/05/2003	Robert Lee	59060US002	9546

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
DONAHOE, CASEY D	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,221	LEE, ROBERT	
	Examiner	Art Unit	
	Casey Donahoe	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/015/03, 4/26/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Examiner acknowledges applicant's Information Disclosures Statement(s), filed 12/05/2003 and 4/26/2005, and has considered the documents listed therein.

Specification

2. The disclosure is objected to because of the following informalities:

The first paragraph on page 7 states that the inner diameter of proximal section 36 of the bore is larger than the outer diameter of the applicator's proximal segment 54. However, a proper interference fit is created when the diameter of the inserted applicator is larger than that of the bore it is inserted into. Examiner suspects the disclosure meant to say the opposite of what it did say with respect to the relative sizes of the diameters.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 11,15, 20, and 21 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Petrich et al. (U.S. 6,592,280).

Regarding claim 1, Petrich et al. disclose a dental material delivery system (Figs. 1-3) comprising:

- an applicator (12) having a proximal segment, a median bending segment (24), and a distal tip segment (26);

- an elongated handle having a proximal end (18), distal end, cylindrical bore, and an annular weakened wall line (28), wherein the proximal segment of the applicator is nonremoveably frictionally mounted within the proximal section of the bore (Column 7, lines 16-25), and the median bending segment of the applicator is aligned generally longitudinally with the annular weakened wall line;

- a desired amount of dental material (not shown);

- an unspecified cap integrally mounted to the handle adjacent the distal end to seal off the distal section of the bore;

wherein the wall of the handle is separable at the annular weakened wall line (Column 4, line 61-63).

Regarding claim 15, the applicator is mounted in the bore by a sealing method (Column 7, lines 16-25), whereby the flow of dental material proximally past the applicator into the proximal section of the bore is prevented.

Regarding claim 20, the elongated handle (Fig. 2) has a generally cylindrical shape, with at least two different outer diameter portions, the proximal outer diameter being smaller than the distal outer diameter.

Regarding claim 21, the handle has a radial extension (36) adjacent its distal end (Fig. 1).

5. Claims 11 and 15 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Petrich and Broyles (U.S. 6,413,087).

Regarding claim 1, Petrich and Broyles disclose a dental material delivery system (Figs. 2-3) comprising:

- an applicator (22) having a proximal segment (28), a median bending segment (32), and a distal tip segment (36);
- an elongated handle having a proximal end (26), distal end(24), cylindrical bore, an annular weakened wall line (40), wherein the proximal segment of the applicator is nonremoveably frictionally mounted within the proximal section of the bore (Column 6, lines 49-53), and the median bending segment of the applicator is aligned generally longitudinally with the annular weakened wall line;
- a desired amount of dental material (38);
- an unspecified cap integrally mounted to the handle adjacent the distal end to seal off the distal section of the bore;

wherein the wall of the handle is separable at the annular weakened wall line (Column 5, line 31-40).

Regarding claim 15, because the proximal section of the applicator is frictionally sealed in the tubing handle, flow of dental material proximally past the applicator into the proximal section of the bore is prevented.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 11-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prantis, Jr. et al. (U.S. 5,860,806) in view of Pietrich et al.

Regarding claim 11, Prantis, Jr. et al. disclose a dental material delivery system (Figs. 2-4) comprising:

- an applicator (12) ;
- an elongated handle having a proximal end (40), distal end(30), cylindrical bore, an annular weakened wall line (35), wherein the proximal segment of the applicator is nonremoveably frictionally mounted within the proximal section of the bore (Column 6, lines 40-51);
- a desired amount of dental material (not shown);
- and an unspecified cap integrally mounted to the handle adjacent the distal end to seal off the distal section of the bore;

wherein the wall of the handle is separable at the annular weakened wall line (Column 6, line 17-22).

Yet, Prantis, Jr. et al. fail to disclose an applicator, which has a median bending segment. Petrich et al., as described earlier, disclose an applicator with a median bending segment, which allows the user to select the angular orientation to facilitate placement of the composition in limited access areas (Column 1, lines 34-39). Petrich et al. also disclose using their applicator as means to seal their container, rather than creating a separate plug. This idea clearly improves the efficiency of the device by combing the applicator and container so that they are already together, presoaking the applicator tip in the desired composition, and reducing the need to manufacture an extra part. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the cap disclosed by Prantis, Jr. et al. to act as the applicator as disclosed by Petrich et al. and also to utilize the median bending segment disclosed by Petrich et al., so that the device would be more efficient, require fewer parts, and have the ability to bend to a desired angular orientation for application.

Regarding claims 12-14, Prantis, Jr. et al. disclose a radial projection in the form of an "outwardly projecting annular snap ring" (46) sized for interference fit with the recess (27) in the inner diameter of the proximal section of the bore. This radial ring, or ribbing, projects in an annular direction around the applicator. It would have been obvious to one of ordinary skill in the art at the time of the invention to duplicate the radial extension, since such is a routine skill and Applicant has not stated that a plurality

of extensions provides any advantage over a single extension, which is capable of sufficiently sealing the bore.

Regarding claim 15, the applicator is mounted in the bore whereby the flow of dental material proximally past the applicator into the proximal section of the bore is prevented (Column 6, lines 29-32).

Regarding claim 20, Prantis, Jr. et al. disclose a handle (Fig. 4), which has a generally cylindrical shape, with at least two different outer diameter portions, the proximal outer diameter (40) being smaller than the distal outer diameter (30).

Regarding claim 21, Prantis, Jr. et al. disclose a handle, which has a radial extension (32) adjacent its distal end (Fig. 2).

8. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrich et al. in view of Walz et al. (EP 1121905).

Petrich et al. disclose the dental material delivery system described earlier, but never explicitly stating the material of manufacture, fail to disclose that part of their system, including the handle and cap, is formed from a cyclic olefin copolymer. Walz et al. disclose a dental materials packaging which is formed of thermoplastic cyclic olefin copolymer for ease of processing by injection-molding as well as high barrier capabilities and chemical resistance to water and polar organic solvents. It would have been obvious to one of ordinary skill at the time of the invention to mold the device disclosed by Petrich et al. from the same cyclic olefin copolymer as disclosed by Walz et al. in order to produce the same advantageous material properties for storing dental material.

9. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrich et al. in view of Rogers (U.S. 5,848,894).

Petrich et al. disclose the dental material delivery system described earlier, but never explicitly stating the material of manufacture, fail to disclose that the applicator is formed from a polyethylene, a polyolefin. Rogers also discloses a dental material delivery system with an applicator, which is formed of polyethylene (Column 2, line 52). Polyethylene provides desirable values for the water absorption, burst value, and oxygen permeability, which are advantageous for containing non-aqueous dental pastes (Column 1, lines 34-44 and Column 2, lines 1-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to mold the device disclosed by Petrich et al. from polyethylene, as disclosed by Rogers, in order to optimize the values of water absorption, burst value, and oxygen permeability.

10. Claims 1-6 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prantis, Jr. et al. in view of Petrich et al. as applied to claims 11-15 and 20-21 above, and further in view of Pieper et al. (U.S. 2001/0019680).

Regarding claim 1, Prantis, Jr. et al. disclose a dental material storage container comprising an elongated handle and Petrich et al. disclose a bendable applicator, which would be obvious to use in combination with the container, as discussed above. Prantis, Jr. et al. specifically disclose that their handle is injection molded (Column 5, lines 65-66). Petrich et al. fail to specifically disclose how the applicator is manufactured because they reference a specific brand. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to also mold the

disclosed applicator because this is a common manufacturing process that is well known in the art. The method of forming the device would inherently include introducing a desired amount of dental material and inserting the applicator into the container, whereby the projection (46) disclosed by Prantis, Jr. et al. would frictionally and nonremoveably engage the bore (Column 6, lines 39-51). However, the combination fails to disclose a distinct cap element to be aligned over the distal end and sealed. Pieper et al. disclose a container and applicator for liquids (Fig. 2) in which a distinct cap (18) is placed on the distal end even though the proximal end is already open. Pieper et al. disclose that this cap has the specific task of forming a hermetic seal with the container so that fluorine gas treatments may be used to provide better product containment within the container. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the container disclosed by Prantis, Jr. et al. with a distinct cap as disclosed by Pieper et al. so that the container may undergo fluorine gas treatments to provide better containment of the dental material. Such a cap would be aligned over the distal open end of the handle and sealed thereto.

Regarding claims 2, 3, and 23-25, the cap disclosed by Pieper et al. includes a longitudinal extension (see Fig. 3), which inherently controls the volume in the bore depending on the size at which the longitudinal extension is formed.

Regarding claims 4 and 22, both the handle disclosed by Prantis (Fig. 1), Jr. et al. and the cap disclosed by Pieper et al. (Fig. 3) include outward radial extensions (36 and unspecified respectively) adjacent the distal open end.

Regarding claim 5, Prantis, Jr. et al. disclose a handle with a distal portion, which extends sufficient distance for bending relative to the proximal portion (Fig. 3)

Regarding claim 6, Pietrich et al. discloses using ultrasonic sealing to seal the proximal portion of the container so that a fluid seal is created. It would have been obvious to one of ordinary skill in the art at the time of the invention to also use ultrasonic sealing to seal the cap disclosed by Pieper et al. to the container so that a fluid seal is created in which no dental material may leak from the container.

11. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prantis, Jr. et al. in view of Petrich et al. and Pieper et al. as applied to claims 1-6 above, and further in view of Walz et al.

Prantis, Jr. et al., Petrich et al., and Pieper et al. disclose the various material container systems described earlier, but fail to disclose that any part of their system, including the handle and cap, is formed from a cyclic olefin copolymer. Walz et al. disclose a dental materials packaging which is formed of thermoplastic cyclic olefin copolymer for ease of processing by injection-molding as well as high barrier capabilities and chemical resistance to water and polar organic solvents. It would have been obvious to one of ordinary skill at the time of the invention to mold the handle and cap from the same cyclic olefin copolymer as disclosed by Walz et al. in order to produce the same advantageous material properties for storing dental material.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prantis, Jr. et al. in view of Petrich et al. and Pieper et al. as applied to claims 1-6 above, and further in view of Rogers.

Prantis, Jr. et al., Petrich et al., and Pieper et al. disclose the various material container systems described earlier, but fail to disclose an applicator, which is formed from polyethylene, a polyolefin. Rogers also discloses a dental material delivery system with an applicator, all of which is formed of polyethylene (Column 2, line 52). Polyethylene provides desirable values for the water absorption, burst value, and oxygen permeability, which are advantageous for containing non-aqueous dental pastes (Column 1, lines 34-44 and Column 2, lines 1-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to mold the material container system, including the applicator, from polyethylene, as disclosed by Rogers, in order to optimize the values of water absorption, burst value, and oxygen permeability.

13. Claims 1-4, 11, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prantis, Jr. et al. in view of Petrich et al. as applied to claims 11-15 and 20-21 above, and further in view of Gueret (U.S. 6,773,187).

Prantis, Jr. et al. disclose a dental material storage container comprising an elongated handle and Petrich et al. disclose a bendable applicator, which would be obvious to use in combination with the container, as discussed above. However, the combination fails to disclose a distinct cap element to be aligned over the distal end and sealed. Gueret teaches a container and applicator for applying a substance (Fig. 26) with a piston-type cap (301 and 301), which is specifically used to seal of the distal end while changing the available volume in the container so that the substance may be applied to the applicator (Column 12, lines 65-67). The cap consists of a longitudinal section and radial extension. It would have been obvious to one of ordinary skill in the

art at the time of the invention to modify the container disclosed by Prantis, Jr. et al. with a piston-type cap disclosed by Gueret so that the available volume may be adjusted as a function of the longitudinal extent of the cap and the applicator will still be able to reach any available substance no matter how small the volume.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wainer (U.S. 6,676,320) is a mascara application device with a cap.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Donahoe whose telephone number is (571) 272-2812. The examiner can normally be reached on Monday - Friday (7:30 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272 -4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/28/05

Casey Donahoe
Examiner
Art Unit 3732

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Ralph A. Lewis
Primary Examiner
Au 3732